

APR 26 2005

K050932

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## 510(k) Summary of Safety and Effectiveness

**General Provisions**

The name of the device is:

Proprietary Name	Common or Usual Name
Distal Volar Radius Anatomical Plate System	Plate Fixation Bone

**Name of Predicate Devices**

The device is substantially equivalent to:

- Distal Volar Radius Plate System (510(k) # K032705 – October 1, 2003) – Hand Innovations, Inc.

**Classification**

Class II.

**Performance Standards**

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

**Indications for Use**

The **Distal Volar Radius Anatomical Plate System** is intended for the fixation of fractures and osteotomies involving the distal radius.

**Device Description**

The modified **Distal Volar Radius Anatomical Plate System** is a set of orthopedic plates and fasteners supplied in a sterilization tray together with several reusable and disposable tools. The set of orthopedic plates and fasteners provided in the sterilization tray consists of the following implantable devices:

- Distal Volar Plates
- Distal Dorsal Nail Plate
- Pegs
- Screws.

Included in the sterilization tray are the following re-useable instruments:

- Peg drivers
- Other standard surgical tools.

In addition, the following are non-reusable instruments included in the sterilization tray:

- F.A.S.T. Guide Technology Drill Guide; and
- Drill bits

**Biocompatibility**

The implantable components of the **Distal Volar Radius Anatomical Plate System** and instruments do not require biocompatibility testing because the titanium used in fabrications meets the requirements of ASTM F 136-96.

**Summary of Substantial Equivalence**

The modified **Distal Volar Radius Anatomical Plate System** is substantially equivalent to the predicate Distal Volar Radius Repair System. The equivalence was confirmed through pre-clinical testing.



APR 26 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Ernesto Hernandez  
COO, Vice President RA/QA  
Hand Innovations, Inc.  
8905 SW Avenue, Suite 220  
Miami, Florida 33176

Re: K050932

Trade/Device Name: Distal Volar Radius Anatomical Plate System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: II

Product Code: LXT

Dated: April 13, 2005

Received: April 14, 2005

Dear Mr. Hernandez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



6- Miriam C. Provost, Ph.D.

Acting Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): \_\_\_\_\_

Device Name: Distal Volar Radius Anatomical Plate System**Indications for Use Statement**

The **Distal Volar Radius Anatomical Plate System** is intended for the fixation of fractures and osteotomies involving the distal radius

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X

OR

Over-The-Counter Use \_\_\_\_\_



Eric H. Thompson, M.D.  
Division of General, Restorative  
and Neurological Devices